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10/827,485	04/19/2004	Makarand P. Gore	200315628-1	3286

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EXAMINER

MERCIER, MELISSA S

ART UNIT	PAPER NUMBER
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1615

NOTIFICATION DATE	DELIVERY MODE
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09/10/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/827,485	Applicant(s) GORE, MAKARAND P.	
	Examiner MELISSA S. MERCIER	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6-5-09.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 9-15, 17-24 and 26-49 is/are pending in the application.
- 4a) Of the above claim(s) 19-24, 26-44 and 47-49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 9-15, 17-18, 45-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Summary

Receipt of Applicants Remarks and Amended Claims filed on June 5, 2009 is acknowledged. Claims 1-5, 9-15, 17-24, and 26-49 remain pending in this application. Claims 19-24, 26-44 and 47-49 remain withdrawn from consideration as reading on non elected subject matter.

Claims 1-5, 9-15, 17-18, and 45-46 remain under prosecution in this office action.

Withdrawn Rejections/Objections

Claim Objections

The objection to claim 3 because of the following informalities: a comma appears to be missing between peptides and an antimicrobial in line 2 has been withdrawn in view of Applicants amendment to the claim correcting the typographical error.

The objection to claim 8 under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form because the term "aqueous" requires that water is present has been withdrawn in view of Applicants cancellation of the claim.

The objection to claim 15 because of the following informalities: a comma appears to be missing between biocide and a viscosity modifier in line 2 has been

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withdrawn in view of Applicants amendment to the claims to correct the typographical error.

Claim Rejections - 35 USC § 112, 1st paragraph

The rejection of claim 1, which recites “wherein said solution has a viscosity sufficiently low that said solution is dispersed by jetting through a jetting fluid dispenser”, has been withdrawn in view of Applicants removal the terminology.

The rejection of claim 1 because it is unclear what “naturally occurring oil” would comprise has been withdrawn due to Applicants removal of the term from claim 1.

The rejection of claim 6 in which the specification has not provided adequate written description for the limitation “wherein said removable oil is configured to be evaporated under the influence of heat or vacuum” has been withdrawn in view of Applicants cancellation of the claim.

The rejection of claim 14 in which the specification has not provided adequate written description for the limitation “edible solvent comprises a salt” has been withdrawn in view of Applicants amendment to the claim to further limit the emulsion to have a salt.

Claim Rejections - 35 USC § 112, 2nd paragraph

The rejection of claim 1 for the recitation of removable oil because it is unclear to the Examiner what oils would fall under a “removable oil” has been withdrawn in view of Applicants removal of the terminology from claim 1.

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The rejection of claim 1, for the term "edible aqueous solution" is also unclear to the Examiner. It is unclear what additional components are required to be in the solution.

The rejection of claim 1 for the recitation of a pharmaceutical has been withdrawn in view of Applicants amendment to the claim to recite "pharmaceutically active agent".

The rejection regarding claims 3 and 10 for the phrase "such as" which rendered the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention has been withdrawn in view of Applicants amendment to the claim to remove the term "such as". However, In view of Applicants amendment to the claim, Applicants attention is directed to the newly applied rejection discussed below.

The rejection regarding claim 6 as being unclear to the Examiner how removable oil can be configured to be evaporated has been withdrawn in view of Applicants cancellation of the claim.

The rejection of claim 10 because it contained the trademark/trade name Pluronic has been withdrawn in view of Applicants removal of the term from the claim.

The rejection of claim 14 because it is unclear to the Examiner what would constitute an edible solvent comprising a salt has been withdrawn in view of Applicants amendment to the claim to recite the solvent further comprises a salt.

Claim Rejections - 35 USC § 102

The rejection of claims 1-10, 13, 15, and 45-46 under 35 U.S.C. 102(b) as being anticipated by Backlund et al. (US 6,004,580) has been withdrawn in view of Applicants amendment to the independent claims to incorporate the limitations of claim 16.

Claim Rejections - 35 USC § 103

The rejection of claims 11-12 and 17-18 under 35 U.S.C. 103(a) as being unpatentable over Backlund et al. (US 6,004,580) in view of Woo (Formulation and physicochemical properties of macro- and micro emulsions prepared by interracial ion-pair formation between, see IDS) has been withdrawn in view of Applicants amendment to the independent claims to incorporate the limitations of claim 16.

Maintained Rejections/Objections

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3, 10, and 15 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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Regarding claims 3 and 10, M.P.E.P. § 2163 states, "An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention...one must define a compound by 'whatever characteristics sufficiently distinguish it'. A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process."

The specification does not describe any species of the instantly claimed derivatives of a water insoluble peptide, an antimicrobial, a PPI, a calcium channel blocker, a beta blocker, an anesthetic, a steroid, an antioxidant, a rennin inhibitor, an alkaloid, a cystostatica, an anti coagulant, a lipid regulating agent, an antidepressant, a neuroleptic, an immunosuppressant, an immunomodulator, an antibiotic, an anti-inflammatory agent, nicotinamide derivatives at p. 11, therefore, it does not describe a sufficient number of species as to convey possession of the entire genus encompassed by derivatives thereof.

Regarding claim 15, Applicant has not provided adequate written description for "a non-acrylic polymer". After a review of the specification, the Examiner was unable to locate any species of polymers that Applicant feels would provide adequate written description for the very broad claim of "a non-acrylic polymer". If Applicant believes such support exists, they are invited to identify such support in the specification as originally filed.

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive. Applicant argues that one skilled in the relative art would readily understand that composition of the derivatives of the various pharmaceuticals and surfactants of the instant claims. The Examiner respectfully disagrees. The specification does not disclose even one example of what would be encompassed by derivatives' thereof or by the term non-acrylic polymers. The skilled artisan has not direction or guidance as to what would be considered to be derivatives of any of the cited components. Applicant also has not demonstrated that every type of polymer would be capable of providing the appropriate results with the scope of the invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 17 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 17, it is unclear what Applicants is claiming by "a pharmaceutical release rate of said solution is varied by varying said naturally occurring oil". It is unclear what the metes and bounds of "varied by varying" is.

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive. It is unclear what the metes and bounds of "varied by varying" are. It is the position of the

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Examiner that any change or alteration is the oil employed would necessarily vary the release rate to some degree, however minute it would be. Clarification is requested.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-2, 5, 13-15, and 45-46 are rejected under 35 U.S.C. 102(b) as being anticipated by Owen et al. (US Patent 5,633,226).

Owen discloses water in oil micro emulsion which readily converts to oil in water emulsion by addition of aqueous fluid to the water in oil micro emulsion (abstract).

The biologically active material composition comprises:

1. an aqueous phase;
2. a pharmaceutically acceptable oil;
3. an oil dispersible surfactant;
4. a water soluble biologically active material;

Additional adjuvant such as stabilizers, coloring agents (claim 15), oil soluble drugs (claim 2) and the like may be added. Each component is disclosed as being suitable for use in the subject and will usually be food grade and/or pharmaceutically acceptable (column 4, lines 49-59).

The water in oil micro emulsions can be liquids at room temperature (column 5, lines 9-11).

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The aqueous phase ranges up to 60% by volume, the oil phase is from about 5-99% by volume, and the surfactant is present from about 1-70% by volume (column 5, lines 16-19).

Regarding claim 5, the oil can include edible oils, such as coconut oil (column 6, lines 27-35).

Regarding claim 13-14, the aqueous phase may comprise other solvents, such as polyhydric alcohols, glycerol, and propylene glycol (column 5, lines 45-48). Salts can also be present, such as when saline is employed.

Owen does not explicitly disclose the solution comprises a viscosity of less than approximately 5 centipoise and a surface tension approximately between 25 and 60 dynes per centimeter. However, since the composition disclosed by Owen is identical in components and percentages within the dependent claims, the physical properties of viscosity and surface tension are necessarily also present or well within the skilled artisan's knowledge to optimize for the intended function. While Owen discloses his composition can be in different forms, such as solids and semi solids, he exemplifies all forms, thereby showing he was in possession of the entire scope of his invention including the solution form. The specification on page 3-4 defines jettable as any material that has properties sufficient to allow the material to be selectively deposited by any digitally addressable inkjet material dispenser. The USPTO does not possess laboratory facilities, therefore, since Owen discloses the same composition, the burden shifts to Applicant to provide evidence that the prior art formulation does not possess the same physical properties as the instant claims.

Newly Applied Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5, 9-15, 17-18, and 45-46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 1 and 45 it is unclear what “configured to be dispensed” encompasses in terms of structural limitations. The specification discloses a jettable solution is “any material that has properties sufficient to allow the material to be selectively deposited by any digitally addressable inkjet material dispenser”. It is unclear to the Examiner how configured to be dispensed by jetting differs from jettable. Clarification is requested.

Regarding claim 3, it is unclear if the pharmaceutically active ingredient is limited to the Markush group presented or if additional active ingredients can be added in. It is suggested that Applicant amend the claim to recite “selected from the group consisting of” in order to clarify the claim language.

Regarding claim 10, Applicant has amended the claim to remove the terminology “such as” but has replaced it with “including”. It is unclear if Applicant is limiting the aromatic sulfonate salts to the cited salts or if they are listed as explanatory and not limiting in nature.

Regarding claim 18, it is unclear what part of the jettable solution is the pharmaceutically active ingredient since according to claim 1, it is a required component, however, claim 18 does not accommodate for it in the percentages.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-4, 9-10, 13-15 and 45-46 are rejected under 35 U.S.C. 102(a) and (e) as being anticipated by Dennis et al. (US Patent 6,623,765).

Dennis discloses micro emulsions and micelle systems for solubilizing drugs (title). A micro emulsion delivery system for water insoluble or sparingly soluble drugs that comprise a long polymer chain surfactant component and a short fatty acid surfactant component (abstract). The microemulsion systems, particularly oil and water, can be used to dissolve substantial concentrations of oil soluble drugs, such as propofol (column 3, line 65 through column 4, line 2).

Regarding claims 2-3, suitable drugs include analgesics, anesthetics, anti-asthmatics, antidiabetics, antifungal, antihypertensives, anti-inflammatories, for example (columns 4-7).

Regarding claim 10, suitable examples of long chain surfactants include lecithin and tweens (column 8, lines 40-64).

Regarding claim 14, salts of lidocaine or tetracaine can also be included (column 10, lines 43-46).

While the reference does not disclose the viscosity or the surface tension of the solution, is it the position of the Examiner that in the absence of a showing otherwise, the composition of Dennis possesses the claimed physical properties.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-3, 10, 13-15, 17, and 45-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barreto (US Patent 7,166,154).

Barreto disclose an ink in a jettable vehicle, wherein the ink is edible (abstract). The vehicle imparts a jettable viscosity (column 4, lines 39-40). The solvent comprises water (column 4, lines 44-45). The vehicle can further comprise reducing oils and solvents (column 5, lines 53-55). Antioxidants can be also be included (column 5, line 56), which Claim 3 discloses as a suitable pharmaceutically active agent. Depending on the particular antioxidant selected would determine its location within the emulsion (i.e. water soluble or oil soluble). Surfactants, including lecithin and tween, are disclosed as emulsifiers (column 5, lines 3-5), thereby meeting the limitation of claim 10.

Regarding claim 14, Colorants, including quinine sulfate and riboflavin phosphate, both of which are salts, are also included (claim 57).

Regarding claims 15, other additives including humectants, waxes, lubricants, body gums and binding varnish, resins, and binders can be incorporated into the solution (column 5, lines 50-55).

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Barreto does not explicitly disclose the solution comprises a viscosity of less than approximately 5 centipoise and a surface tension approximately between 25 and 60 dynes per centimeter. However, since the composition disclosed by Barrett comprises the same components as the instant claims and is used for an identical purpose, the physical properties of viscosity and surface tension are necessarily also present or well within the skilled artisan's knowledge to optimize for the intended function. The specification on page 3-4 defines jettable as any material that has properties sufficient to allow the material to be selectively deposited by any digitally addressable inkjet material dispenser. The USPTO does not possess laboratory facilities, therefore, since Barreto discloses the same composition, the burden shifts to Applicant to provide evidence that the prior art formulation does not possess the same physical properties as the instant claims.

Barreto does not require the solution be an emulsion. However, based on the disclosure of Barreto in which oils are optional components, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have prepared the ink as an emulsion based on the suggestion by Barreto.

Claims 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barreto (US Patent 7,166,154) in view of Woo (Formulation and physicochemical properties of macro- and micro emulsions prepared by interfacial ion-pair formation between, see IDS).

The teachings of Barreto are discussed above and applied in the same manner.

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Barreto does not teach the use of or amount to use of a surfactant comprising an ion-pair formation between an amino acid and a fatty acid, wherein the amino acid comprises L-arginine or L-lysine and the fatty acid comprises stearic acid or oleic acid.

Woo teaches that water-in-oil and oil-in-water emulsions can be prepared using stearic acid and L-arginine or L-lysine (pg. 105-109).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use the components taught by Woo to emulsify the composition taught by Barreto because these naturally occurring fatty acids and amino acids are extremely safe and ideal for pharmaceutical use (Woo, pg. 103). Furthermore, determining result effective amounts of the ingredients beneficially taught by the cited references is deemed merely a matter of judicious selection and routine optimization, which is well within the purview of the ordinary artisan.

Conclusion

Due to the new grounds of rejection presented in this office action, this action is made Non-Final.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA S. MERCIER whose telephone number is (571)272-9039. The examiner can normally be reached on 8:00am-4:30pm Mon through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melissa S Mercier/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615